HFA 305

FREEDOM OF INFORMATION SUMMARY

SEP 22 1999

I. IDENTIFICATION.

ANADA Number: **200-233**

Sponsor:

Alpharma Animal Health Division
Highway 71 North
P.O. Box 309
Lowell, Arkansas 72745

Trade Name: LINCO SOLUBLE

Generic Name: Lincomycin Hydrochloride Soluble Powder 40 %

Marketing Status: OTC

Pioneer Product: Lincomycin Hydrochloride Soluble Powder (Lincomix Soluble Powder) NADA 111-636.

II. INDICATIONS FOR USE

For the treatment and control of swine dysentery (bloody scours) in swine and for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin in broiler chickens.

III. DOSAGE FORM, ROUTE OF ADMINISTRATION AND RECOMMENDED DOSAGE:

Dosage Form: Soluble Powder

Route of Administration: Lincomycin Hydrochloride Soluble powder is administered orally in the drinking water.

Recommended Dosage:

Swine:

For treatment, the drug is administered to swine at 3.8 mg lincomycin per pound of body weight per day for a maximum of 10 days.

Broiler Chickens:

The drug is administered to broiler chickens at a dose rate of 64 mg of lincomycin per gallon of drinking water for a maximum of 7 days.

IV. TARGET ANIMAL SAFETY AND EFFECTIVENESS

Under the provisions of the Federal Food, Drug and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA. Ordinarily the ANADA sponsor shows the generic product is bioequivalent to the pioneer, and the ANADA relies on the target animal safety, effectiveness, and human food safety data in the new animal drug application (NADA) for the pioneer. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement of an in vivo bioequivalence study ((Fifth GADPTRA Policy Letter, 55 FR 24645, June 18, 1990; Bioequivalence Guidance, 1996, 61 FR 26182, May 24, 1996).

Based on the formulation characteristics of the generic product, Alpharma Animal Health Division was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product LINCO SOLUBLE (lincomycin hydrochloride soluble powder). The generic product is administered as an oral solution, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient as finally administered. The pioneer product is Lincomix Soluble Powder (lincomycin hydrochloride soluble powder) the subject of Pharmacia & Upjohn Company's (formerly The Upjohn Company) NADA 111-636, approved on January 2, 1983.

V. HUMAN FOOD SAFETY

Tolerance:

The tolerances established for the pioneer product apply to the generic product. Tolerances for lincomycin of 0.6 ppm in liver and 0.1 ppm in muscle are established for swine. A tolerance for tissue residues in chickens is not required (21 CFR 556.360).

Withdrawal Times:

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal times for lincomycin hydrochloride soluble powder are established under 21 CFR 520.1263c:

six days for swine and zero days for broiler chickens. Lincomycin soluble powder is not for use in layer and breeder chickens.

Regulatory Method for Residues:

The regulatory analytical method for detection of residues of the drug is a microbiological test using *Sarcina lutea* (ATCC 9341). The method is on display in FDA's Freedom of Information Public Room, 5600 Fishers Lane, Rockville, MD 20857. The method is also on file at the Center for Veterinary Medicine, HFV-199, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855.

VI. AGENCY CONCLUSIONS

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) satisfies the requirements of section 512(n) of the FFDCA and demonstrates that Lincomycin Hydrochloride Soluble Powder when used under the proposed conditions of use, is safe and effective for its labeled indications.

Attachments:

generic product labeling
pioneer product labeling

INDICATIONS - Swine:
Linco Soluble is indicated for the treatment of swine dysentery (bloody scours).

INDICATIONS - Broiler Chickens:
Linco Soluble is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

This Packet Contains
as active ingredient:
Lincomycin hydrochloride,
equivalent to lincomycin . . . . . 16 g

ANADA 200-233, Approved by FDA

For oral use in Swine and Broiler Chickens only

Net Weight
1.4 oz (40 Grams)

Restricted Drug
Use only as directed (California)

ALPHARMA.
Animal Health Division

Alpharma Inc.
One Executive Drive, Fort Lee, New Jersey 07024

AHF-016 9807

SWINE: Directions for use
DOSAGE: Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per lb of body weight per day.
TREATMENT PERIOD. The drug should be administered for a minimum of 5 consecutive days beyond the disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin premix at 100 g lincomycin per ton of complete feed as the sole ration according to label directions

ADMINISTRATION: This packet will medicate 64 gallons of drinking water providing 250 mg/gallon A dose of 3.8 mg lincomycin per lb of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water when pigs are consuming 1.5 gallons per 100 lbs of body weight per day. Under these circumstances the concentration of lincomycin required in medicated water may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each of which affects water consumption. For use in automatic water proportioners, prepare the stock solution by dissolving 2 packets in 1 gallon of water; then adjust the proportioner to deliver 1 oz of stock solution per gallon of drinking water. NOTE: After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin premix at 40 g lincomycin per ton of complete feed as the sole ration.

BROILER CHICKENS: Directions for use
DOSAGE: Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water.
TREATMENT PERIOD. Start medication as soon as the diagnosis of necrotic enteritis is determined. If improvement is not noted within 24 to 48 hours,

Linco
Soluble

consult a licensed veterinarian or veterinary diagnostic laboratory to determine diagnosis. The drug should be administered for 7 consecutive days.

ADMINISTRATION: This packet will medicate 250 gallons of drinking water providing 64 mg/gallon.

NOTE. After water medication is discontinued, a recommended control program for necrotic enteritis consists of feeding lincomycin premix at 7 g lincomycin per ton of complete feed.

CAUTIONS:

1. Discard medicated drinking water if not used within 2 days. Fresh stock solution should be prepared daily.
2. If clinical signs of bloody scours (watery, mucoid or bloody stools) have not improved during the first 5 days of medication, discontinue treatment and redetermine the diagnosis.
3. Occasionally, swine fed lincomycin may within the first 2 days of the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within 5 to 8 days without discontinuing the lincomycin treatment.
4. Not for use in swine weighing more than 250 pounds.
5. Do not allow rabbits, hamsters, guinea pigs, horses or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.
6. Do not use the water treatment and the feed treatment simultaneously.
7. Not for use in layer and breeder chickens.

WARNINGS:

1. Do not slaughter swine for human consumption for 6 days following last treatment.
2. No drug withdrawal period is required before slaughter of birds receiving Linco Soluble at the approved level of 64 mg per gallon of drinking water.
3. Not for human use

Store at Controlled Room Temperature 15° to 30° C (59° to 86° F)

Take Time

Observe Label Directions

Linco

Lincomycin Hydrochloride Soluble Powder

Color profile: Disabled
Composite

WJC# 24226 / 24227 BLACK PMS 307 BLUE

Lincomycin Hydrochloride
Soluble Powder
Antibacterial

Linco Soluble

Follow directions for use and mixing instructions on packet label

CAUTION: Not for human use / for oral use in swine and broiler chickens only

Lot no:

Exp.date:

Contents: 50 packs, 1.4 oz (40 g) each

ALPHARMA
Animal Health Division

ANADA 200-233, Approved by FDA

Alpharma Inc.
One Executive Drive, Fort Lee, New Jersey 07024

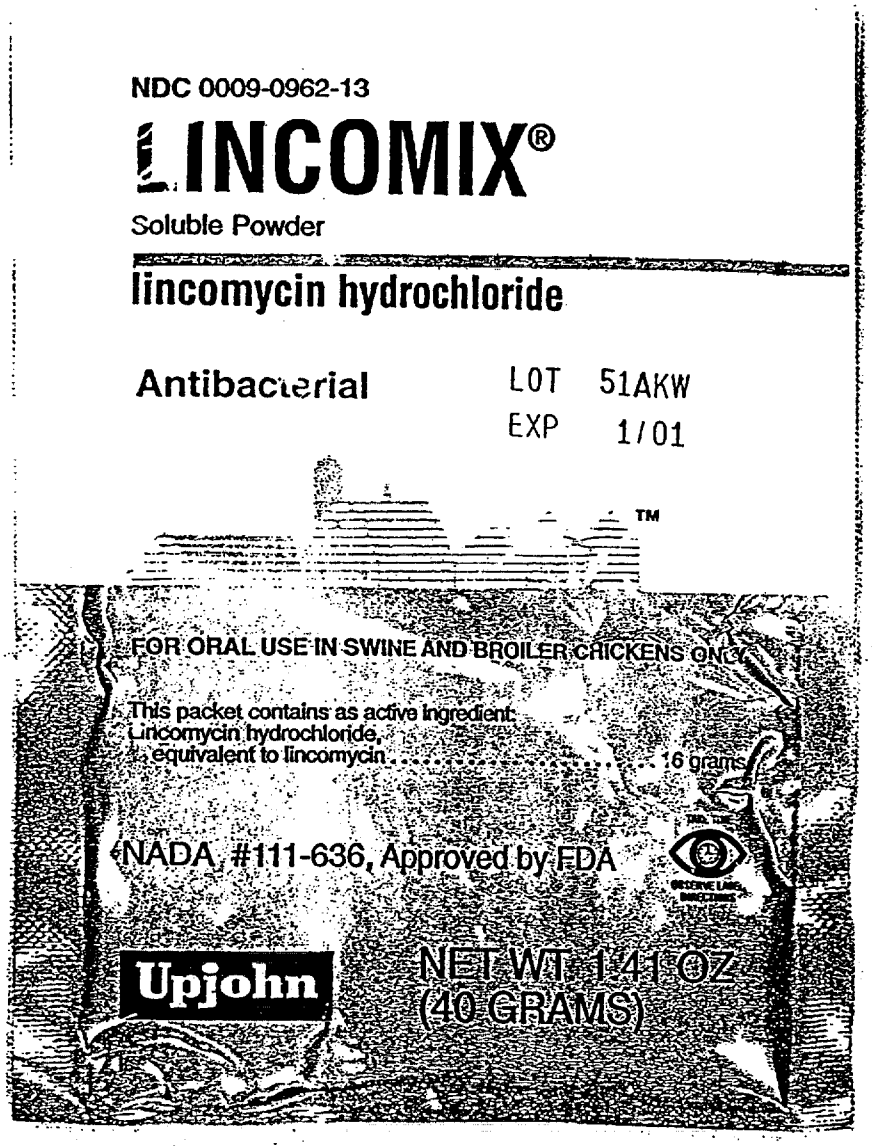
AHL-108 9807

[illegible]
Thursday, July [illegible], 1999 [illegible]

Pioneer

(3) LABELING (CONT.):

PIONEER LABEL 1.41 oz (40 G) FRONT PANEL



pioneer

(3) LABELING (CONT.):

PIONEER LABEL 1.41 OZ. (40 G) REAR PANEL

Restricted Drug—Use Only as Directed (California)

SWINE: Directions for Use

INDICATION: LINCOMIX Soluble Powder is indicated for the treatment of swine dysentery (bloody scours).

DOSAGE: Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day.

TREATMENT PERIOD: The drug should be administered for a minimum of 5 consecutive days beyond the disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days. If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin premix at 100 grams lincomycin per ton of complete feed as the sole ration according to label directions.

ADMINISTRATION: This packet will medicate 64 gallons of drinking water providing 250 mg/gallon. A dose of 3.8 mg lincomycin per pound of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water when pigs are consuming 1.5 gallons per 100 lbs of body weight per day. Under these circumstances the concentration of lincomycin required in medicated water may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each of which affects water consumption.

For use in automatic water proportioners, prepare the stock solution by dissolving two packets in one gallon of water; then adjust the proportioner to deliver 1 ounce of stock solution per gallon of drinking water.

NOTE: After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin premix at 40 grams lincomycin per ton of complete feed as the sole ration.

BROILER CHICKENS: Directions for Use

INDICATION: LINCOMIX Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

DOSAGE: Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water.

TREATMENT PERIOD: Start medication as soon as the diagnosis of necrotic enteritis is determined. If improvement is not noted within 24 to 48 hours, consult a licensed veterinarian or veterinary diagnostic laboratory to determine diagnosis. The drug should be administered for 7 consecutive days.

ADMINISTRATION: This packet will medicate 250 gallons of drinking water providing 64 mg/gallon.

NOTE: After water medication is discontinued, a control program for necrotic enteritis may be followed by feeding lincomycin premix at 2 grams lincomycin per ton of complete feed.

CAUTIONS

1. Discard medicated drinking water if not used within 2 days. Fresh stock solution should be prepared daily. 2. If clinical signs of bloody scours (watery, mucoid or bloody stools) have not improved during the first 6 days of medication, discontinue treatment and redetermine the diagnosis. 3. Occasionally, swine fed lincomycin may within the first two days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within five to eight days without discontinuing the lincomycin treatment. 4. Not for use in swine weighing more than 250 pounds. 5. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. 6. Do not use the water treatment and the feed treatment simultaneously. 7. Not for use in layer and breeder chickens.

WARNINGS

1. Do not slaughter swine for human consumption for 6 days following last treatment.
2. No drug withdrawal period is required before slaughter of birds receiving LINCOMIX Soluble Powder at the approved level of 64 mg per gallon of drinking water.
3. Not for human use.

Store at Controlled Room Temperature 15° to 30° C (59° to 86° F).
The Upjohn Company • Kalamazoo, MI 49001, USA

814 518 003

690446

pioneer

(3) LABELING (CONT.):

PIONEER LABEL 2.82 OZ. (80 G) FRONT PANEL

NDC 0009-0962-18

LINCOMIX®

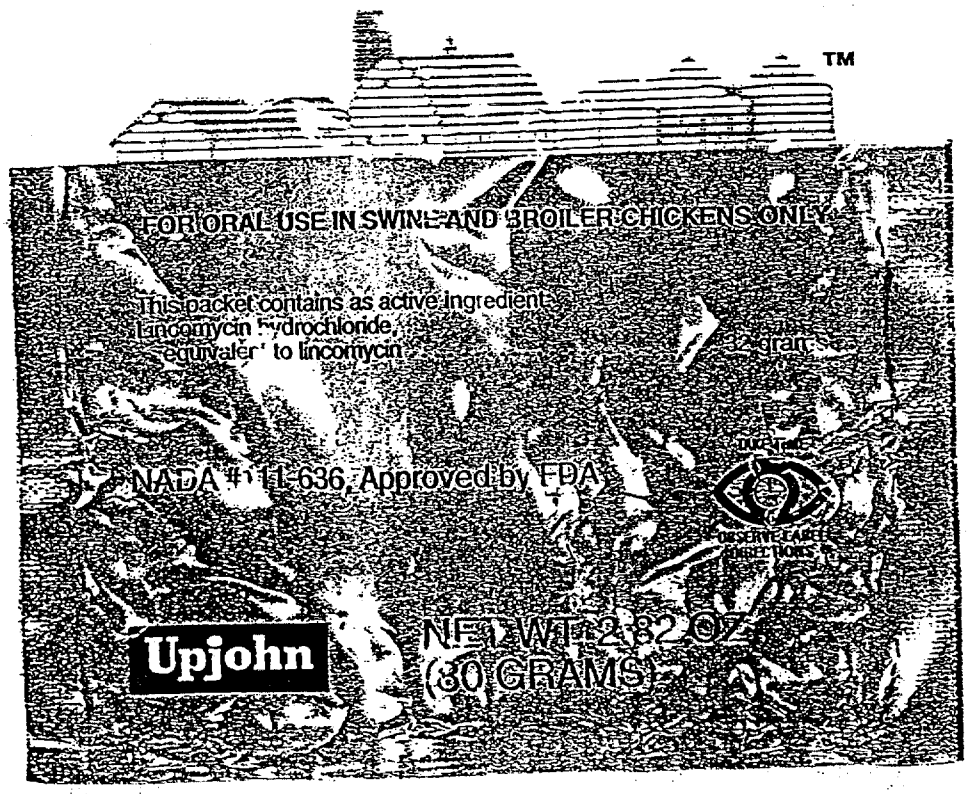
Soluble Powder

lincomycin hydrochloride soluble powder

LOT 87AAX

EXP 6/00

Antibacterial



Pioneer

(3) LABELING (CONT.):

PIONEER LABEL 2.82 OZ. (80 G) REAR PANEL

Restricted Drug—Use Only as Directed (California)

SWINE: Directions for Use

INDICATION: LINCOMIX Soluble Powder is indicated for the treatment of swine dysentery (bloody scours).

DOSAGE: Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day.

TREATMENT PERIOD: The drug should be administered for a minimum of 5 consecutive days beyond the disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days. If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin premix at 100 grams lincomycin per ton of complete feed as the sole ration according to label directions.

ADMINISTRATION: This packet will medicate 128 gallons of drinking water providing 250 mg/gallon. A dose of 3.8 mg lincomycin per pound of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water when pigs are consuming 1.5 gallons per 100 lbs of body weight per day. Under these circumstances the concentration of lincomycin required in medicated water may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each of which affects water consumption. For use in automatic water proportioners, prepare the stock solution by dissolving one packet in *one* gallon of water; then adjust the proportioner to deliver 1 ounce of stock solution per gallon of drinking water.

NOTE: After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin premix at 40 grams lincomycin per ton of complete feed as the sole ration.

BROILER CHICKENS: Directions for Use

INDICATION: LINCOMIX Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

DOSAGE: Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water.

TREATMENT PERIOD: Start medication as soon as the diagnosis of necrotic enteritis is determined. If improvement is not noted within 24 to 48 hours, consult a licensed veterinarian or veterinary diagnostic laboratory to determine diagnosis. The drug should be administered for 7 consecutive days.

ADMINISTRATION: This packet will medicate 500 gallons of drinking water providing 64 mg/gallon.

NOTE: After water medication is discontinued, a control program for necrotic enteritis may be followed by feeding lincomycin premix at 2 grams lincomycin per ton of complete feed.

CAUTIONS

1. Discard medicated drinking water if not used within 2 days. Fresh stock solution should be prepared daily. 2. If clinical signs of bloody scours (watery, mucoid or bloody stools) have not improved during the first 6 days of medication, discontinue treatment and redetermine the diagnosis. 3. Occasionally, swine fed lincomycin may within the first two days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within five to eight days without discontinuing the lincomycin treatment. 4. Not for use in swine weighing more than 250 pounds. 5. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. 6. Do not use the water treatment and the feed treatment simultaneously. 7. Not for use in layer and breeder chickens.

WARNINGS

1. Do not slaughter swine for human consumption for 6 days following last treatment.
2. No drug withdrawal period is required before slaughter of birds receiving LINCOMIX Soluble Powder at the approved level of 64 mg per gallon of drinking water.
3. Not for human use.

Store at Controlled Room Temperature 15° to 30° C (59° to 86° F)
The Upjohn Company • Kalamazoo, MI 49001, USA 815 934 000

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